

Exhibit F

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4 IN RE: ETHICON, INC., PELVIC) Master File No.
REPAIR SYSTEM PRODUCTS) 2:12-MD-02327
LIABILITY LITIGATION) MDL 2327

5 THIS DOCUMENT RELATES TO
6 PLAINTIFFS:

7 Diane Kropf
Case No. 2:12-cv-01202 JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

8 Judy Williams
Case No. 2:13-cv-00657

9 Myra Byrd
10 Case No. 2:12-cv-00748
11 Angela Coleman
Case No. 2:12-cv-01267

12 Susan Thamen (Reeves)
13 Case No. 2:12-cv-00279
14 Donna Zoltowski
Case No. 2:12-cv-00811

15
16
17 DEPOSITION OF JOSEPH M. CARBONE, M.D.
18 GENERAL PROLIFT
19 Wednesday, March 16, 2016
20 Danville, Virginia
21 9:20 p.m.
22

23 Reported by: Karen K. Kidwell, RMR, CRR, CLR
24 GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
25 deps@golkow.com

1 Q. -- were sufficient to inform doctors who
2 perform pelvic mesh surgeries of the risk of the
3 product?

4 A. Yes.

5 Q. Do you know what standards Ethicon applied
6 in terms of what needed -- what warnings needed to be
7 included in the IFU about Prolift?

8 A. The standards that Ethicon applied?

9 Q. Yes.

10 A. I'm not familiar with what the standards
11 Ethicon applied, no.

12 Q. Now, you've stated before that it was your
13 general practice to read the IFU of a medical device
14 before using it the first time; is that correct?

15 A. My general practice.

16 Q. Did you assume, when you read that IFU,
17 that the IFU was disclosing to you each of the risks
18 and complications the company knew with the kit you
19 were using?

20 MR. ROSENBLATT: Object to form.

21 THE WITNESS: I got, you know, do -- did I
22 assume that the company -- repeat it again, very
23 slowly.

24 BY MR. FAES:

25 Q. Did you assume when you read an IFU before

1 a medical device company to include in an IFU?

2 MR. ROSENBLATT: Object to form.

3 Misstates as far as what they require.

4 THE WITNESS: I mean, did they -- they
5 have guidelines, I think, but I don't think
6 there are any requirements. Are there
7 requirements?

8 BY MR. FAES:

9 Q. Well, that's my question to you. Have you
10 made any effort before your deposition today to find
11 out what FDA regulations require a medical device
12 company to put in an IFU?

13 MR. ROSENBLATT: Object to form.

14 THE WITNESS: Again, it's my understanding
15 that there aren't any specific requirements. I
16 think there are guidelines.

17 So have I made any effort? Am I -- have I
18 made any effort to find out anything that
19 doesn't exist? I mean, you know, it's a hard
20 question to answer.

21 BY MR. FAES:

22 Q. So let me ask you another way.

23 A. Yes.

24 Q. Have you made any effort before today to
25 find out what FDA guidelines require a medical device